REMARKS

The Office Action dated June 3, 2004 has been carefully reviewed and the following amendments and comments are made in response thereto. In view of the above amendments and following remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims. Applicant respectfully submits that no new matter has been introduced by the claim amendments. Claims 13-20 have been amended to correct typographic errors and antecedent basis. Support for the amendments can be found throughout the specification and original claims.

Summary of Final Office Action

1. Claims 13-20 were rejected under 35 U.S.C. § 112, first paragraph, as based on a disclosure which is allegedly not enabling.

2. Claims 13-20 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

The Rejection under 35 U.S.C. § 112, First Paragraph

Claims 13-20 are rejected under 35 U.S.C. § 112, first paragraph, as based on a disclosure which has been alleged as not being enabling because "the feature of the size of the particulates is critical or essential to the practice of the invention" (page 2 of the Office Action). Claims 13-20 are also rejected under 35 U.S.C. § 112, first paragraph, for scope of enablement. The Examiner alleges that the specification, "while being enabling for particles of a specific size, does not reasonably provide enablement for particles of any size (page 2 of the Office Action)." The Examiner further alleges that the term "cohesive multicellular particulates" would require undue experimentation for one skilled in this art to determine which size would work in the instant invention and the term "reads on an entire organ to two cells, neither of which are likely to work in the claimed invention."

Applicant respectfully disagrees with the Examiner's interpretation of the term and contends that the particulate size is not critical in the instant cell culture method. The Examiner has failed to advance any evidence or technical reasoning why a particular size of the particulates is critical for practice of the invention. When rejecting a claim under § 112, first paragraph, the Patent Office bears the "initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the disclosure." *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). To assert that the disclosure is not enabling with respect to the scope of a claim sought to be patented, the Examiner must identify evidence or technical reasoning substantiating those doubts. *Id.* and M.P.E.P. § 2164.04. Without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling. The Examiner has not provided any evidence indicating Applicant's disclosure would not enable those skilled in the art to practice the claimed invention.

In the absence of any evidence from the Examiner showing that a specific size of the particulate would not work, Applicant respectfully submits that the method of cell culture of the present invention is enabled and disclosed in the instant specification. The present invention discloses a method of culturing tumor cells from cancer patients for the purpose of identifying and monitoring the progress of the disease. The cell culturing method disclosed in the specification involves the steps of collecting a tissue specimen from a patient and separating the specimen into cohesive multicellular particles by mechanical means such as scissors, scalpels or incisor blades (see, for example, page 16 at line 35). The specification teaches that the process employing cross cutting is important because the technique maximizes the growth of malignant cells from the tissue sample and thus optimizes the subsequent tissue culture assay.

Applicant respectfully submits that the Examiner has improperly placed undue focus upon the size of particulates. Applicant's specification teaches that the size of the particulates is not critical or essential as suggested by the sentence,"[p]referably, but not necessarily, the tumor particulates each measure 1 mm^3 (page 16, line 30 of the specification, emphasis added)." Thus, absent evidence from the Examiner supporting the currently unsubstantiated arguments on the

issue of particulate size, the rejection should be withdrawn. Reconsideration and withdrawal of the rejection is respectfully requested.

Based on the detailed disclosure of the cell culturing procedure in the specification, one of skill in the art would not interpret the term "cohesive multicellular particulates" to encompass "an entire organ." The specification teaches that the tissue source is from a tumor biopsy. The weight of the tissue from the biopsy is in the milligram range. In the examples of the specification, the tissue usually weighs 50 mg (Examples 1-7) to 100 mg (Example 8). The tissue sample also has to be minced. The ordinary meaning of the word "mince," according to Webster's Dictionary, is to cut into very small pieces. It is thus untenable for the Examiner to stretch the interpretation of the term so far as to encompass a 10-12 pound severed human head, or, an entire organ. While it may appear that the Examiner attempts to give the broadest reasonable interpretation to the claims (claims should be given their broadest reasonable interpretation), such interpretation should also be consistent with the specification (see M.P.E.P. § 2111). Applicant respectfully submits that one of the ordinary skilled in art would not reasonably interpret the term "cohesive multicellular particulate" to encompass "an entire organ" because it is inconsistent with what is taught in the specification.

One of ordinary skill, using the methods taught in the specification, would be able to easily determine whether "two cell" particulates would work as claimed. The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived would be inoperative or operative with expenditure of no more effort than is normally required in the art.

The Examiner further cites *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) as support for the rejection of Applicant's claims. However, the conclusion that the quantity of experimentation is undue, based on the particulates as claimed, is set forth without any factual or evidentiary basis. As discussed above, there is no teaching in the specification that particulate size is critical to the

success of cell culture. In addition, the invention is directed to culture of cells from normal or tumor tissues, which is essentially a routine task for the person of ordinary skill in the art.

The characterization of the amount of guidance as "inefficient to predict the sizes" is believed to be without consideration of the level of skill in the art. Applicant submits that the guidance on how to obtain the minced particulates provided in the specification is detailed. For example, the specification provides clear guidance as to the methods to mince and transfer the specimen. (see, *e.g.*, page 16 and elsewhere in the specification). As discussed above, there is no need to predict the size of the particulates. Following the guidelines provided in the specification the cell culture can be done without undue experimentation.

The Examiner seemingly requires that Applicant provide examples for each and every size of the particulate for cell culture as the Examiner states that only a single size of particulates is disclosed. It is respectfully submitted that Applicant is not required to disclose every size proposed in their disclosure, as compliance with 35 U.S.C. § 112, first paragraph does not turn on whether every embodiment is disclosed (see M.P.E.P. § 2164.02). The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without `undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Applicant asserts the pending claims are of a scope which is clearly enabled by the specification and that ample guidance and examples for the practice of the claimed invention is provided.

As discussed above, a skilled artisan, using the information provided in the specification coupled with the information and techniques available and known in the art, would be able to practice the claimed methods. Accordingly, the full scope of each of the claims is enabled by the specification. Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 13-20 under 35 U.S.C. § 112, first paragraph.

The Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 13-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is respectfully traversed.

Claims 13-20 stand rejected because the term "cohesive multicellular particulates" is not understood by the Examiner "as to what specimen is separated into (page 5 of the Office Action)." The Examiner contends that such a term "reads on no separating to forming two cell particulates."

Applicant respectfully submits that the claims containing the term are not indefinite. As discussed above, one of skill in the art would interpret the term to describe particulates which result from the method by which they are prepared.

The Examiner further contends that the sole difference between the present application and its parent is the "size of the sample." It is noted that the parent application, U.S. Pat. No. 5,728,541, claims a "particulate size," not a "sample" size. Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

Applicant respectfully requests reconsideration of the subject application in view of the amendments to the claims and the above remarks. It is respectfully submitted that this application is now in condition for allowance. Should the Examiner feel that there are any issues outstanding after consideration of this amendment, the Examiner is requested to contact the Applicant's undersigned representative.

If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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Respectfully submitted,
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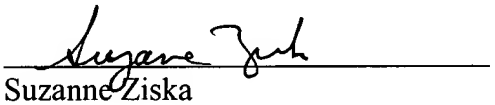

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